

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0125]

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Certifier R. LEDESMA

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, New and Revised General Test Procedures, Revised Policy, and Revised Guideline; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, proposed new and revised general test procedures, a proposed revised policy, and a proposed revised guideline. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients, as well as new monographs, new and revised test procedures, a revised policy, and a revised guideline are being prepared by The National Academies, Institute of Medicine (IOM), Committee on Food Chemicals Codex (the committee). This material is expected to be included in the next publication of the Food Chemicals Codex (the fifth edition). The committee is in the process of revising the entire fourth edition of the Food Chemicals Codex and its supplements to produce a comprehensive fifth edition, scheduled for public release in the autumn of 2003. Comments are being invited on the changes proposed in this notice or on any other item in the fourth edition of the Food Chemicals Codex or its supplements.

DATES: Submit written or electronic comments by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO–3038, Food and Nutrition Board, Institute of Medicine, 2001 Wisconsin Ave. NW., Washington, DC 20007. (NOTE: This is a temporary address to be used for sending responses to this notice by U.S. mail only.) Submit all responses to be delivered by other carriers to the Committee on Food Chemicals Codex/FO–3038, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418. Submit electronic comments to fcc@nas.edu. Copies of the proposed new Food Chemicals Codex specification monographs, proposed changes to certain monographs, proposed new and revised general test procedures, and proposed revisions to a policy and to a guideline, may be obtained upon written request from the IOM or may be examined at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs, test procedure, policy or guideline desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ricardo A. Molins, Project Director/FO–3038, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or Paul M. Kuznesof, Office of Food Additive Safety (HFS–205), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3009.

SUPPLEMENTARY INFORMATION: By contract with the IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of August 8, 2000 (65 FR 48521), January 22, 2001 (66 FR 6624), as corrected on February 9, 2001 (66 FR 9710), and June 13, 2001 (66 FR 31936), FDA announced

that the committee was considering new and revised monographs, new and revised general test procedures, new and revised test solutions, and revisions to a policy for inclusion in the third supplement to the fourth edition of the Food Chemicals Codex. The third supplement to the fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in November 2001. It is available for sale from NAP (1-800-624-6242; 202-334-3313; FAX 202-334-2451; Internet <http://www.nap.edu>); 2101 Constitution Ave. NW., Lockbox 285, Washington, DC 20055.

The committee is in the process of revising the entire fourth edition of the Food Chemicals Codex and its supplements to produce a comprehensive fifth edition. This revision encompasses policies, general monographs, flavor chemical monographs, and general tests and procedures. Notice of items that have undergone substantive revision will be given in the **Federal Register** and also made available electronically. FDA now is announcing that the committee is soliciting comments and information on proposed new Food Chemicals Codex specification monographs, on proposed changes to certain monographs, on proposed new and revised general test procedures, on a proposed revised policy and on a proposed revised guideline; as well as comments and information on any other item in the fourth edition of the Food Chemicals Codex or its supplements. These new and revised monographs, new and revised test procedures, and revised policy and guideline are expected to be published in the fifth edition of the Food Chemicals Codex. If comments are received that cannot be addressed by the committee before publication of the fifth edition, the new monographs or test procedures, revised monographs or test procedures, or revised policy or guideline affected will be considered for the first supplement to the fifth edition of the Food Chemicals Codex. Copies of the proposed items may be obtained upon written request from IOM at the address listed previously or through the Internet at <http://www.iom.edu/fcc>.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new or revised monographs, new or revised test procedures, revised policy, or revised guideline into FDA regulations without ample opportunity for public comment. If FDA decides

to propose the adoption of new monographs and test procedures and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications to be included in the 2 proposed new monographs, 75 proposed revisions of current monographs, 2 proposed new general test procedures, 2 proposed revised general test procedures, proposed revised policy, and proposed revised guideline included in this document. The committee notes that in all of the monographs included in this document, the heavy metals (such as lead) specification and test have been removed, new heavy metals specifications and tests have been added as necessary, and taste and scent references have been removed from all descriptions, except those for flavors. In all of these proposed documents, the language has been modified to be more specific and consistent.

I. Proposed New Monographs

Ferrous Glycinate

Transglutaminase

II. Current Monographs to which the Committee Proposes to Make Revisions

Acetic Acid, Glacial (FEMA Number added; Description revised; Lead specifications revised)

Aconitic Acid (Synonym and FEMA Number added; Description and Identification revised; Lead specifications added; Tridodecylamine and Ultraviolet Absorbance specifications deleted)

Adipic Acid (Lead specifications added)

Agar (Description revised)

Aluminum Ammonium Sulfate (Lead requirement and test revised; Assay test revised; Fluoride test moved to Appendix IIIB)

Aluminum Potassium Sulfate (Lead specifications added; Assay test revised; Fluoride test moved to Appendix IIIB)

Aluminum Sodium Sulfate (Formula deleted; CAS Numbers added and revised; Lead specifications added; Assay test revised; Fluoride test moved to Appendix IIIB)

Aluminum Sulfate (Lead requirement and test revised; Assay test revised)

Ammonium Bicarbonate (Lead specifications added)

Ammonium Sulfate (Lead specifications added)

Aspartame (Lead specifications added)

Azodicarbonamide (Lead requirement and test revised)

Balsam Peru Oil (CAS Number added)

Basil Oil, European Type (CAS Number added; Description revised)

Beeswax, White (Functional Use in Foods and Lead specifications revised)

Beeswax, Yellow (Functional Use in Foods and Lead specifications revised)

Bergamot Oil, Coldpressed (FEMA Number added; Angular Rotation requirement revised; Lead specifications deleted)

Butane (Description revised)

1,3-Butylene Glycol (Synonym added; Lead specifications added)

Calcium Ascorbate (Arsenic and Fluoride specifications deleted)

Calcium Bromate (CAS Number added; Lead specifications revised)

Calcium Chloride (Functional Use in Foods revised)

Calcium Glycerophosphate (Lead requirement revised)

Calcium Hydroxide (Lead specifications revised)

Calcium Oxide (Lead requirement revised)

Calcium Sulfate (Lead specifications added)

Canola Oil (Synonyms revised; CAS Number added; Functional Use in Foods modified; Sulfur test modified)

Carnauba Wax (Functional Use in Foods and Lead specifications revised)

beta-Carotene (INS Number revised; Lead specifications added)

Carrot Seed Oil (CAS and FEMA numbers added)

Cassia Oil (CAS and FEMA numbers added)

Castor Oil (Synonym added; Description revised; Identification Test B added; Lead specifications added)

Cellulose, Powdered (Structure added; Functional Use in Foods revised; Lead specifications added)

Cinnamon Bark Oil, Ceylon Type (CAS and FEMA Numbers added)

Cinnamon Leaf Oil (CAS Number revised; FEMA Number added)

Copper Gluconate (Identification Test B revised; Lead specifications revised)

Cottonseed Oil (Unhydrogenated) (Description revised; Functional Use in Foods revised; Arsenic specifications deleted)

beta-Cyclodextrin (Substance Name now hyphenated; Lead test revised; Microbial Limits Specifications deleted)

Dammar Gum (Microbial Limits deleted)

Decanoic Acid (FEMA Number added; Description and Functional Use in Foods revised)

Diacetyl Tartaric Acid Esters of Mono- and Diglycerides (Synonym, INS Number, and CAS Numbers added; Description revised; Lead specifications added; Assay for Tartaric Acid, Acid Value, and Fatty Acids tests revised)

Diatomaceous Earth (CAS Number added, revised; Description revised; Arsenic specifications revised; Loss on Drying requirement revised)

Ethylene Dichloride (Lead specifications added)

Ferrous Fumarate (Synonym added; Description revised; Lead requirement and test revised; Mercury test moved to Appendix IIIB)

Ferrous Gluconate (Structure and Description revised; Lead requirement and test revised; Mercury test moved to Appendix IIIB)

Flavor Chemicals, Specifications for Flavor Chemicals (Note added; rest of notes renumbered sequentially)

Food Starch, Modified (Arsenic specifications deleted; Lead test revised)

Fumaric Acid (FEMA Number added; Description revised; Lead specifications added)

Gibberellic Acid (Lead specification revised)

Glycerol Ester of Gum Rosin (Lead and Ring-and-Ball Softening Point requirements revised)

Glycerol Ester of Partially Dimerized Rosin (Ring-and-Ball Softening Point requirement revised)

Glycerol Ester of Partially Hydrogenated Wood Rosin (Ring-and-Ball Softening Point requirement revised)

Glycerol Ester of Polymerized Rosin (Ring-and-Ball Softening Point requirement revised)

Glycerol Ester of Tall Oil Rosin (Ring-and-Ball Softening Point requirement revised)

Glyceryl-Lacto Esters of Fatty Acids (Synonym and INS Number added; Total Lactic Acid test revised)

Glyceryl Monooleate (Synonyms, Structure, INS Number, and FEMA Number added; Description and Functional Use in Foods revised)

Glyceryl Monostearate (CAS Number added)

Glyceryl Palmitostearate (Lead specifications added)

Glyceryl Tristearate (Synonym, Formula Weight, and Lead test revised)

Guar Gum (INS Number added; Description revised; Arsenic specifications deleted; Lead specifications revised)

4-Hexylresorcinol (Lead specifications revised)

Isobutane (CAS Number added; Description and Identification Test B revised)

Isobutylene—Isoprene Copolymer (Description and Total Unsaturation requirement revised)

Lard (Unhydrogenated) (Functional Use in Foods revised; Insoluble Matter renamed; Hexane-Insoluble Matter test added; Unsaponifiable Matter specifications added)

Lemongrass Oil (CAS and FEMA numbers added; Angular Rotation requirements revised; Steam-Volatile Oil specifications deleted)

Magnesium Sulfate (Formula Weight added, CAS Numbers added and revised, Lead limit added)

Myrrh Oil (CAS Number revised; FEMA Number added; Angular Rotation requirement revised)

Pectins (Functional Use in Foods revised; Identification test revised; Arsenic specifications deleted; Acid-Insoluble Ash, Degree of Amide Substitution and Total Galacturonic Acid in the Pectin

Component, and Total Galacturonic Acid in Pectin Component specifications renamed; Total Insoluble Substances specifications added)

Pentaerythritol Ester of Partially Hydrogenated Wood Rosin (Ring-and-Ball Softening Point requirement revised)

Pentaerythritol Ester of Wood Rosin (Ring-and-Ball Softening Point requirement revised)

Potassium Gibberellate (CAS Number added, Lead limit revised)

Potassium Metabisulfite (Lead specifications added; Selenium requirement revised; Assay test revised)

Propyl Gallate (Lead specifications added)

Pyridoxine Hydrochloride (Lead specifications added)

Soy Protein Concentrate (Lead test modified)

III. Proposed New General Test Procedures

Cadmium Limit Test (new)

Transglutaminase Activity (Appendix V: Enzyme Assays)

IV. Proposed Revised General Test Procedures

Curcumin Content, Appendix VIII: Oleoresins (Standard Preparation deleted; Sample Preparation and Procedure revised)

Hexane-Insoluble Matter, Appendix VII: Fats and Related Substances (Sample size increased to 100 g, and test scaled accordingly; test moved from the Lecithin monograph to Appendix VII (test also added to Lard and Tallow monographs))

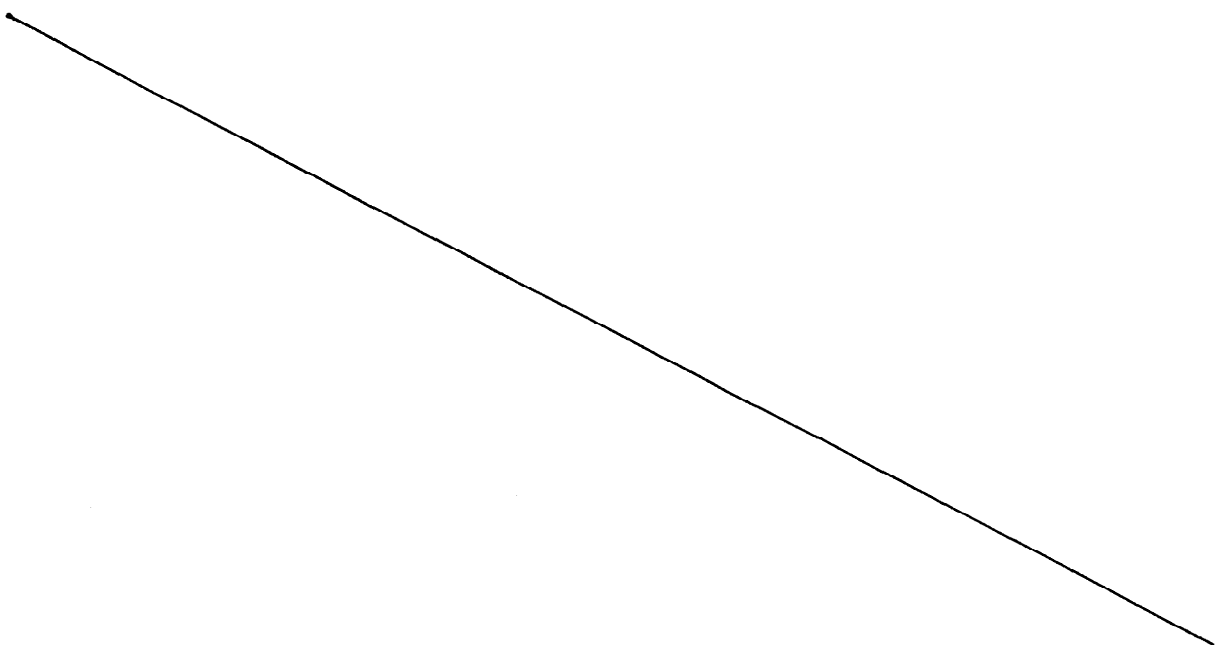
V. Proposed Revised Policy and Guideline

Microbiological Attributes (Policy) (rewritten)

Fluoride Limits (Guideline) (rewritten)

VI. Comments and Electronic Access

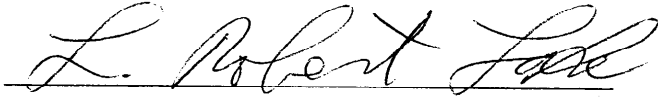
Interested persons may submit to the Committee on Food Chemicals Codex written and electronic comments regarding the monographs, general test procedures, policy and guideline identified in this notice, or comments on any other item in the fourth edition of the Food Chemicals Codex or its supplements, by [*insert date 60 days after date of publication in the **Federal Register***]. Timely submission will allow comments to be considered for the fifth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the fifth edition, but will be considered for the first supplement to the fifth edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs, the general test procedures, the policy, or the guideline listed in this notice, as well comments on any other item in the fourth edition of the Food Chemicals Codex or its supplements, are to be submitted to the Committee on Food Chemicals Codex (see **ADDRESSES**). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. The committee staff will forward a copy of each comment to the Dockets Management Branch (see **ADDRESSES**). Received comments may be seen in the Dockets Management



Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of the proposed changes may also be obtained through the Internet at <http://www.iom.edu/fcc>.

Dated: 5/21/02

May 21, 2002.



L. Robert Lake,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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